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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/977,547

10/15/2001

Kristy Peterson

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01/12/2004

KIMBERLY-CLARK WORLDWIDE, INC.
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EXAMINER

CROSS, LATOYA I

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

Office Action Summary	Application No.	Applicant(s)	
	09/977,547	PETERSON ET AL	
	Examiner	Art Unit	
	LaToya I. Cross	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 22 September 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

This Office Action is in response to Applicant's remarks filed on September 22, 2003.

Claims 1-66 are pending in the instant application.

Drawings

Corrected drawings were received on September 22, 2003. These drawings are acceptable and overcome the objection set forth in the previous Office Action.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-47 of copending Application No. 09/977,546. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims do not recite "a separator that permits the first well to be separated from the second well", as is recited in 09/977,546. However, the instant claims recite "a first well and a second well". The two wells would obviously require some separator between the two; otherwise, two distinct wells would not exist.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 14, 16-18, 22, 24-26, 28, 29, 31, 33-35, 29-39, 41, 42, 44, 45, 47, 48, 53, 55, 56 and 58-62 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,182,191 to Fan et al.

Fan et al teach a sampling device for collecting transporting and storing a solid or liquid sample. The device includes carrier having two specimen application wells (20) for receiving a specimen sample. The device also include two sample sticks (24) for handling the specimen as recited in claims 1, 17, 18, 28, 41, 42 and 56. A front cover (10) covers both the sample wells and the sample sticks, as recited in claims 3, 22, 31, 33, 44, 45, 58, and 59. Indicia for documenting the patient's information is disposed on the front cover of the carrier shown in figures 1 and 5, as recited in claims 14, 24, 34, 47 and 60. At col. 9, lines 31-46, Fan et al teach that the device may be made from plastic material, as recited in claims 16, 26, 39, and 53. With respect to the shape of the device, as recited in claims 25, 35, 48 and 61, Fan et al show a rectangular shaped device in figures 1-4. With respect to the location of the sample handling tools (sample sticks), figures 4-6 show the sample sticks removably attached to the device.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b) in view of the teachings of Fan et al.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 5-13, 19, 20, 36-38, 50-52, 63, 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan et al in view of US patent 3,653,389 to Shannon.

The disclosure of Fan et al is described above. Fan fails to teach sample handling tools having a pair of cooperating arms attached to one another.

Shannon teaches disposable forceps which are manufactured of plastic material, as recited in claim 63. The forceps of Shannon have cooperating arms (1), which are connected to one another by a connecting section (2). The connection section forms a projection, as recited in claims 9 and 64. The connection section is equivalent to Applicants' claimed rear portion and the teeth (6) of the forceps of Shannon are equivalent to Applicants' claimed tip portion, as recited in claims 6, 19, 37 and 51. The forceps of Shannon have a bowed (arcuate) section 4 and another bowed section near the teeth of the device, as recited in claims 10, 12, 20, 38, 52 and 63.

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The tip end of the forceps has a spiked portion and a flat portion, as recited in claim 8. Shannon teaches that forceps having this structure may be easily and cheaply manufactured. They provide the user with a good grip and also are well suitable for engaging objects conventionally used in hospitals and clinics.

It would have been obvious to one of ordinary skill in the art to use the forceps of Shannon in the sample collection device of Fan et al to provide the user with a device more suitable for grasping small samples tightly and a device that is more comfortable to use.

8. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fan et al in view of US Patent 5,593,851 to Jackson.

Fan et al does not provide a sample handling device having a fork at its end.

Jackson teaches a kit for collecting tissue samples. The kit includes a means for handling the tissue sample (36) having a forked end (42). Jackson teaches that the forked end of the specimen handling device allows the sample to be controllably moved with the collection device, without piercing the sample. It would have been obvious to one of ordinary skill in the art to use a forked sample handling device in the collection device of Fan et al to provide the user with a device to better handle the sample without destroying it.

9. Claims 2, 4, 21, 23, 30, 32, 43, 46, 49 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan et al in view of US Patent 5,955,032 to Kelly et al.

Fan et al does not provide for a "plug" for partially sealing a chamber/well in the device. Fan et al does teach that collection cup may be attached to the device for holding larger volumes of sample.

Kelly et al teach a collection container having a stopper-like closure (160). The closure provides a cover for the sample contained within the collection container, to ensure that the sample is not contaminated or accidentally lost. It would have been obvious to one of ordinary skill in the art to include a plug/stopper on the collection cup of Fan et al to ensure safe keeping of the sample until time for use.

Response to Arguments

10. Applicant's arguments filed September 22, 2003 have been fully considered but they are not persuasive. Applicants' arguments are primarily directed to the Fan et al references. First, Applicants argue that Fan et al fail to teach a first well and a second well. Second, Applicants argue that the sample sticks of Fan are not specimen handling tools and are not adapted to be disposed about at least a portion of a well.

With respect to a first and second well, Applicants argue that the specimen application areas (20) of Fan et al are not wells. In response, with respect to the wells of Fan et al, the reference teaches that specimen application areas (20) are holes that are punched into panel (14) and filled with porous material (col. 6, lines 49-56). The reference goes on to describe the specimen application areas (20) as having a predefined "depth" for collecting a specimen (col. 7, lines 11-41). Further, Fan et al teach that the panels are made of material, such as cardboard or plastic and the porous material together with the openings define a specimen volume (col. 9, lines 31-46). Thus, given the teachings of Fan et al as a whole, it appears, that the specimen application areas (20) are indeed sample wells, in their broadest sense, especially since the reference teaches that the areas (20) define a specimen volume.

With respect to the claimed specimen handling tools, Fan et al teach sample transferring sticks (24) for handling specimen. According to figure 4, the transferring sticks are disposed on the back side of the sample application areas (20). While, it may be true that the transferring sticks of Fan et al may be removed by the user and Applicants' specimen handling tool is not removed, the manner in which the device operates is not sufficient to allow the claims to be patentable over Fan et al, since Fan et al does teach the structural elements claimed by Applicants. Applicants' claims do not structurally differ from the device taught by Fan et al.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Examiner.

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January 2, 2004


Jill A. Warden
Supervisory Patent Examiner
Technology Center 1700